

Engelhardt et al.
Serial No. 09/727,349
Filed: November 30, 2000
Page 2 (Transmittal - February 8, 2001)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

FEB 13 2001

TECH CENTER 1600/2900

Applicant(s): Engelhardt et al.

Serial No. 09/727,349

Group Art Unit: 1655

Filed: November 30, 2000

Examiner: Arun Chakrabarti, Ph.D.

Title: NOVEL PROCESS, CONSTRUCT AND CONJUGATE FOR
PRODUCING MULTIPLE NUCLEIC ACID COPIES

FILED BY EXPRESS MAIL

COPY

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

Transmitted herewith is a Response To Restriction Requirement And Election
of Invention Under 37 C.F.R. §1.143 in the above-identified patent application.

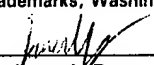
The fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
Total	90	Minus	90	= 0	X \$ 9	\$ 0
Indep	6	Minus	6	= 0	X \$ 40	\$ 0
()	First Presentation of Multiple Dependent Claims				+ \$135	\$ 0
	TOTAL ADDITIONAL FEE					\$ 0

- () Charge Deposit Account No. 05-1135 in the amount of \$ _____.
- () A check in the amount of \$ _____ is attached.
- (X) The Commissioner is hereby authorized to charge payment of the following
fees associated with this communication or credit any overpayment to
Deposit Account No. 05-1135: any filing fees under 37 C.F.R. §1.16 for the
presentation of extra claims and any patent application processing fees under
37 C.F.R. §1.17.

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. EL531126058US
Deposit Date February 8, 2001
I hereby certify that this paper and the attachments
herein are being deposited with the United States Postal
Service "Express Mail Post Office to Addressee" service
under 37 CFR 1.10 on the date indicated above and is
addressed to the Commissioner of Patents and
Trademarks, Washington DC 20231.


James L. Rogers
Reg. No. 44,305


Date


Engelhardt et al.
Serial No. 09/727,349
Filed: November 30, 2000
Page 2 (Transmittal – February 8, 2001)

Copies are being provided in triplicate.

Also enclosed: _____

February 8, 2001
Date

Respectfully submitted,



James L. Rogers
Registration No. 44,305
Attorney for Applicant(s)

ENZO DIAGNOSTICS, INC.
c/o Enzo Biochem, Inc.
527 Madison Avenue (9th Fl.)
New York, New York 10022
Tel. (212) 583-0100

Attorney's Docket No.: Enz-52(D1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE RECEIVED

FEB 13 2001

TECH CENTER (600Q2540)

Applicants: Engelhardt et al

Serial No. 09/727,349

Filed: November 30, 2000

Title: **NOVEL PROCESS, CONSTRUCT AND
CONJUGATE FOR PRODUCING
MULTIPLE NUCLEIC ACID COPIES**

Group Art Unit: 1655

Examiner: Arun Chakrabarti,
Ph.D.

527 Madison Avenue, 9th Floor
New York, New York 10022
February 8, 2001

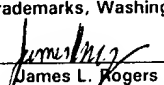
FILED BY EXPRESS MAIL

Honorable Commissioner
of Patents and Trademarks
Washington, D.C. 20231

**RESPONSE TO RESTRICTION REQUIREMENT
AND ELECTION OF INVENTION UNDER 37 C.F.R. §1.143**

Dear Sirs:

Pursuant to 37 C.F.R. §1.143, Applicants hereby respond to the restriction requirement set forth in the February 5, 2001 Office Action issued in connection with the above-identified application. This response is being timely filed within the thirty (30) day shortened statutory period for response also set forth in the February 5, 2001 Office Action.

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No. EL531126058US	
Deposit Date <u>February 8, 2001</u>	
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.	
 James L. Rogers Reg. No. 44,305	<u>2/8/01</u> Date

REMARKS

This is a response to the restriction requirement dated February 5, 2001.

In the February 5, 2001 Office Action, the Examiner required restriction under 35 U.S.C. §121 to one of the following inventions:

- I. Claims 1-51, drawn to method of *in vitro* polymerase chain reaction, classified in Class 435, subclass 91.2+;
- II. Claims 52-72 and 81-90, drawn to nucleic acid constructs, classified in Class 536, subclass 22.1+; and
- III. Claims 73-80, drawn to method of *in vivo* polymerase chain reaction, classified in class 435, subclass 91.1.

In response, Applicants hereby elect, with traverse, the invention of Group I, claims 1-51, drawn to method of *in vitro* polymerase chain reaction. Applicants respectfully request reconsideration and withdrawal of the restriction requirement in view of the remarks set forth below.

Under M.P.E.P. §803, two criteria are necessary in order for a restriction requirement between patentably distinct inventions to be proper:

- 1) The inventions must be independent or distinct as claimed; and
- 2) There must be a serious burden on the Examiner if restriction is not required.

The claims represented by Groups I, II, and III form a single general inventive concept which should be properly examined in the same application. Applicants contend that a diligent search of the art for any of these three groups would necessitate a review of the art – at least in part – for the other corresponding groups. Methods of amplifying by *in vitro* and *in vivo* polymerase chain reaction should logically entail a search of nucleic acid constructed used therewith. Particularly, in the case of Groups I and III, these claims are drawn to the same class and nearly the same subclass.

In the event that the restriction requirement is maintained, the above remarks notwithstanding, Applicants and Assignee respectfully request modification of the restriction requirement by combining the claims for the subject matter classified in Group I and in Group III. This would result in the following two groups:

Group I, claims 1-51 and 73-80; drawn to method for *in vitro* and *in vivo* polymerase chain reaction, classified in Class 435, Subclasses 91.1 and 91.2 + and

Group II, claims 52-72 and 81-90, drawn to nucleic acid constructs, classified in Class 536, Subclass 22.1 + .

The claims represented by Groups I and III also form a single general inventive concept - methods of amplifying using polymerase chain reaction - which should be properly examined in the same application. Applicants contend that a diligent search of the art for either of these two groups would probably necessitate a review of the art – at least in part – for the other corresponding group. This position is particularly supported by the fact that each of the claim groups are classified in Class 435, and the subclasses are nearly identical.

It is respectfully submitted that a search of the prior art for the process defined by Groups I and III (claims 1-51 and 73-80), as suggested above, would not place a serious burden on the Patent Office or the Examiner in light of the search that will already be required for the provisionally elected process claims of Group I. Applicants are firmly of the opinion that a search for the invention of Group I, diligently undertaken, would inevitably overlap with the subject matter covered by Group III. Moreover, it is submitted the instant restriction requirement will only serve to duplicate the search efforts of the Patent Office and other examiners in future filings necessitated by the requirement, in the event it is maintained. By combining Groups I and III together, the search efforts will be more efficient. Furthermore, the Assignee will not have to incur additional refiling costs for two divisional applications, one additional refiling being more reasonable.

Applicants reserve the right to prosecute the non-elected claims of Group II, claims 52-72, 81-90 and Group III, claims 73-80 in a separately filed divisional application.

* * * * *

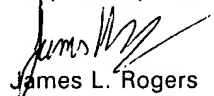
SUMMARY AND CONCLUSION

Claims 1-90 were previously pending in this application. In response to the restriction requirement, Applicants have elected, with traverse, the invention of Group I, claims 1-51. In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the restriction requirement, or in the alternative, modification of the restriction requirement to two groups as set forth above.

No fee or fees are believed due in connection with this paper. In the event that any fee or fees are due, however, The Patent and Trademark Office is authorized to charge Deposit Account 05-1135 for any such fees, and to credit any overpayment therein.

If it would be helpful in expediting examination of all of the claims in this application, the Examiner is respectfully requested to telephone the undersigned attorney at (212) 583-0100 to discuss the subject application.

Respectfully submitted,



James L. Rogers
Registration No. 44,305
Attorney for Applicants

ENZO DIAGNOSTICS, INC.
c/o Enzo Biochem, Inc.
527 Madison Avenue (9th Fl.)
New York, New York 10022
(212) 583-0100